DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 26, 2015

Combat Medical Systems, LLC
% Calley Herzog
Biologics Consulting Group, Inc,
400 N Washington St., Suite 100
Alexandria, VA 22314

Re: K141685
Trade/Device Name: Combat Ready Clamp (CroC)
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 17, 2014
Received: December 18, 2014

Dear Calley Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141685

Device Name
Combat Ready Clamp (CRoC™)

Indications for Use *(Describe)*
The CRoC™ is indicated for use in the battlefield to control difficult bleeds in the inguinal and axilla areas. The CRoC is also indicated for use in the battlefield as a last resort for life threatening bleeds of the carotid artery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the CroC™ is provided below.

Device Common Name:	Vascular Clamp
Device Proprietary Name:	Combat Ready Clamp (CRoC™)
Submitter:	Combat Medical Systems, LLC 5555 Harrisburg Industrial Park Drive Harrisburg, NC 28075
Contact:	Calley Herzog Biologics Consulting Group, Inc. Consultant Email: cherzog@bcg-usa.com Phone: 720-883-3633
Date Prepared:	**January 26, 2015**
Classification Regulation:	21 CFR 870.4450, Class II, Vascular Clamp
Panel:	Cardiovascular
Product Code:	DXC
Predicate Device:	K130482, Combat Ready Clamp (CRoC™)

Indication for Use:

The CRoC™ is indicated for use in the battlefield to control difficult bleeds in the inguinal and axilla areas. The CRoC is also indicated for use in the battlefield as a last resort for life threatening bleeds of the carotid artery.

Device Description:

The CRoC™ is designed to be used by emergency medical personnel in the battlefield. The device is designed to control bleeding in anatomical areas where standard tourniquets cannot be used. The device can be used instead of manual pressure, allowing the medic to attend to other injuries. The CRoC™ is used to control a difficult bleed for up to 4 hours until the injured can be transferred to evacuation personnel or other medical personnel for further treatment.

Performance Data:

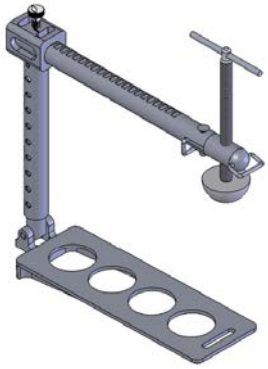
To establish substantial equivalence the CRoC™ was tested with a cadaver model to show that it was capable of stopping simulated vessel blood pressure on neck area wounds.

Substantial Equivalence:

The subject device is the exact same device as that cleared in K130482. There have been no changes to the design or materials of the device. The additional indication for life threatening bleeds of the carotid artery does not alter the intended use. The safety concerns are the same as

those for other anatomical areas and the revised instructions for use address any additional concerns related to treating life threatening bleeding in the neck area. The technological characteristics are compared to the predicate device in Table 1.

Table 1: Device Comparison Table

	New Device	**Predicate Device**
510(k) Number	K141685	K130482
Device Name	Combat Ready Clamp (CRoC™)	Combat Ready Clamp (CRoC™)
Manufacturer	Combat Medical Systems, LLC	Combat Medical Systems, LLC
Picture		
Indication	The CRoC™ is indicated for use in the battlefield to control difficult bleeds in the inguinal and axilla areas. The CRoC is also indicated for use as a last resort for life threatening bleeds of the carotid artery.	The Combat Ready Clamp (CRoC™) is indicated for use in the battlefield to control difficult bleeds in the inguinal and axilla areas.
Dimensions	8”x12 1/4”x9” (extended)	8”x12 1/4”x9” (extended)
Weight	1.25 lbs with disc attached	1.25 lbs with disc attached

Substantial Equivalence Summary

Based on technological characteristics and performance data the CRoC™ has been shown to be substantially equivalent to the predicate device, the Combat Ready Clamp as cleared in K130482.